
HACCP (Hazard Analysis and Critical Control Point)

CEIA SpA

Introduction

The HACCP system is a tool originally designed on commission from NASA to guarantee the safety of foods in spaceflight. Nowadays HACCP is applied in the chain of food production from the harvesting of produce to the final consumer. HACCP improves food safety, rationalizes resources and allows a quick response to problems that arise; it also complements official controls and encourages international trade by increasing trust in food safety and providing producers with a legal safeguard.

HACCP is recognized by the World Health Organization (WHO) as the most efficient way of preventing disease or accidents deriving from contaminants or alterations in food products. It is a preventive approach for controlling the safety of foods rather than quality control.

The HACCP system has the following phases:

- Dividing a global process into successive individual processes;
- Analyzing each individual process to identify where hazards might occur (Hazard analysis);
- Deciding what control measures can prevent or eliminate the potential hazard, or reduce it to an acceptable level;
- Establishing where it is indispensable to check the safety of the food in question, e.g. the CCPs in which the control systems are operating;
- Establishing the critical limit for the critical control points;
- Determining how to monitor the CCPs and what corrective measures should be taken in the event of rejection;
- Establishing the procedures to check that the whole system is working;

- Documenting all the above (HACCP plan) and keeping records.

The above is contained in the 7 principles published by Codex¹ e NACMCF².

The “principles” define the successive steps for application of the HACCP:

1. Carry out the risk analysis;
2. Determine the CCPs (Critical Control Points);
3. Establish the critical limits;
4. Establish a monitoring system;
5. Establish the corrective measures to be taken when monitoring indicates that a particular CCP is not under control;
6. Establish procedures to check that the HACCP system is working efficiently;
7. Establish the documentation of the system concerning all procedures and records.

Application of the HACCP concepts requires careful study of the production or preparation of foods. Monitoring, adoption of corrective measures, checks and records are the concrete steps taken to achieve product safety.

5 elements have been identified to enable an HACCP program to be put into effect:

1. *HACCP Study* – in which the elements of the HACCP system are established in compliance with the 7 principles;

2. *HACCP Plan* – the result of the HACCP Study. This is a document prepared in accordance with the 7 principles to ensure control of the significant risks to food safety
3. *HACCP Team* – the personnel who carry out the HACCP Study, usually 4-6 people from different areas of expertise (e.g. chemists, biologists, engineers etc.).
4. *HACCP System* – implementation of the HACCP Plan in the workplace;
5. *HACCP Documentation and Record* – to show that the system is in place and working.

Figure 1 shows how a qualified HACCP Team begins to develop the HACCP Plan:

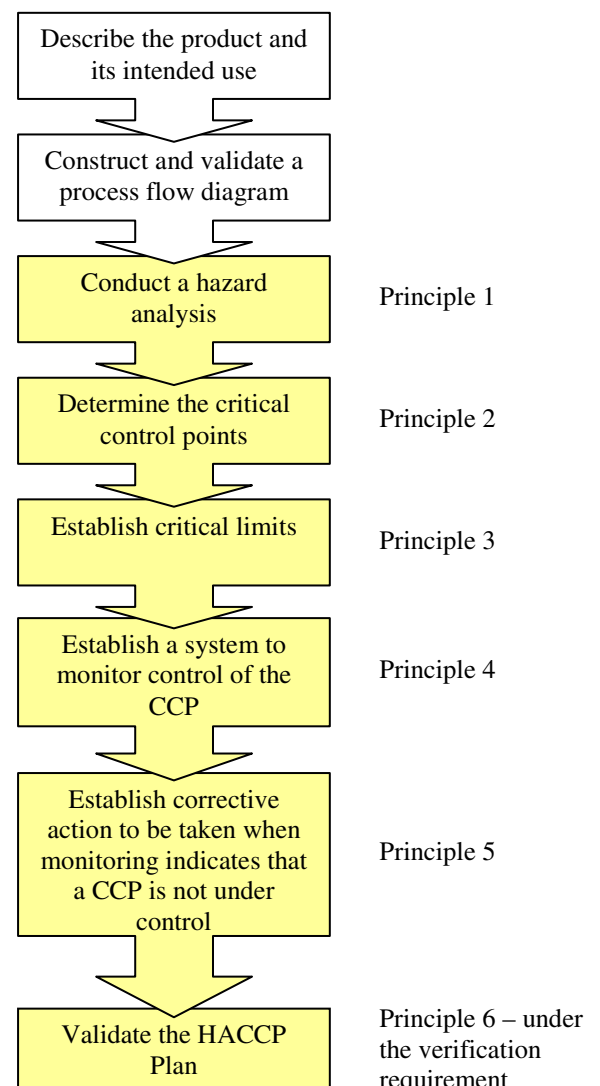


Fig. 1

¹ The Codex Alimentarius Commission was created in 1963 by the FAO (Food and Agriculture Organization) and the WHO (World Health Organization). The main aim of this program is to protect consumer health and ensure correct procedures in the food industry.

² National Advisory Committee on Microbiological Criteria for Foods, the first organization in the United States organically to develop the principles of HACCP as we know them today, was founded in 1988 and is made up of members of numerous federal agencies, among which should be mentioned the Food and Drug Administration (FDA), the Center for Disease Control and Prevention (CDC) and the Food Safety Inspection Service (FSIS).

One of the first tasks of the workgroup is to describe the product, so that all members of the group have a sound knowledge of the same and of the processes that need to be studied.

They then carry out a risk analysis, in which they try to identify all the hazards involved in each phase. In the HACCP system, the word “Hazard” is understood as something unacceptable because it may harm the consumer; this might be a biological, chemical or physical agent in the food.

The hazards are checked at the CCPs. The CCPs may be raw materials, positions, processes, procedures, files, product formulations and so on. A Critical Control Point is a phase into which a preventive measure may be introduced where this is essential or to eliminate a hazard.

To ensure that hazards are adequately controlled, critical limits must be defined. These limits set the levels above which certain agents become unacceptable. In some cases the critical limits are defined by the operators, in others by the public authorities.

The effectiveness of the preventive measures must be checked or, in HACCP terminology, monitored. The monitoring system must be defined for each CCP. The monitoring system includes the method, the

equipment to be used, the moment when the check is to be made (e.g. at the beginning or end of production) and the frequency. Corrective action to the monitoring system may be necessary to ensure that only conforming products reach the consumer.

The objective of the verification procedures is to control the effectiveness of the HACCP system and to apply methods, procedures, tests and other assessments in addition to monitoring in order to determine conformity with the HACCP plan.

The HACCP system must be documented and records kept to demonstrate its effectiveness.

It is important to point out that the Metal Detector is considered a Critical Control Point. This follows from the CCP definition set out above: a metal contaminant undetected during the production process constitutes a non-eliminable hazard for the consumer.

As a reference text we would mention *HACCP, Sara Mortimore and Carol Wallace*, where an example of an HACCP program is included showing how the steps described above are applied to the “Metal Detection” phase:

Hazard to be controlled	Control measure	Critical limits	Monitoring			Corrective actions	
			Procedure	Frequency	Responsibility	Procedure	Responsibility
Contamination by ferrous metal	Metal Detection and rejection	Absence of all ferrous metals more than 2.5 mm in diameter. Metal Detectors correctly calibrated and working continuously	The 2.5 mm test samples must be rejected when placed in the middle of the product	At the beginning and end of the work shift, and every 60 minutes	Line operator	Recheck product starting from the last test passed	Line manager

Table 1

Analysis of the

HACCP System principles

Principle 1 – *Analysis of the hazards associated with each phase of the process.*

The list of hazards in the food field includes the presence of physical contaminants, one of which is metal fragments from machinery which carry out procedures such as cutting, mincing etc.

Principle 2 – *Determining the Critical Control Points (CCPs).*

From the hazard analysis it is evident that the Metal Detector is a Critical Control Point, to which the subsequent principles set out under the HACCP plan must therefore be applied.

Principle 3 – *Establishing the critical limits.*

With regard to the interception of metal fragments, establishing a critical limit means ensuring the absence of metal fragments above a set diameter within the product.

Principle 4 – *Establishing the monitoring system.*

Monitoring the Critical Control Point means checking that the critical limits established in the previous step are observed.

Monitoring systems must have the following fundamental characteristics:

1. The equipment must be carefully calibrated to ensure sufficient accuracy. (With regard to this point, *Mortimore and Wallace 1998*, specify that the Metal Detectors must be programmable with adequate sensitivity for the product).
All CEIA THS Metal Detectors are provided with an product Autolearn procedure, which allows the machine to calibrate the operational parameters for maximum accuracy.
This procedure consists of the automatic acquisition of the product's characteristics via some transits through

the Metal Detector so as to compensate for the effects of typical conductivity.

The parameters that are automatically set during this procedure are as follows:

- "TX Program" (parameter TP), which determines the optimum work point to minimize the interference signal;

- "Sensitivity" (parameter SE).

For products with chemico-physical characteristics that change slowly over time, it is also possible to set the "TP Follower" parameter: the Metal Detector automatically repositions the optimum work point in accordance with the variations in the product by modifying the TP parameter.

2. Monitoring must allow management of the production process and notification of any deviation from the specifications in time for corrective measures to be taken before the product is put on the market.

CEIA THS Metal Detectors allow comprehensive management of the Critical Control Point within the process. Each individual element is checked, and in the event of alarm the contaminated product is ejected automatically. The detector is also fitted with an ejection confirmation sensor which blocks the conveyor line if a contaminated product has not been ejected correctly.

Principle 5 – *Establishing the corrective measures.*

According to the definition supplied by NACMCF, a corrective measure is one that should be taken for all food produced in the period in which a deviation may occur due to an out-of-control CCP.

All CEIA THS Metal Detectors include a self-diagnosis system which halts the production line if the detector is not operating correctly. This prevents there being contaminated food downstream of the Critical Control Point. When the Metal Detector goes into fault status, optical and acoustic signals attract the attention of the personnel responsible for resetting it.

CEIA also supplies the THS Production software, which allows management of one or

more Metal Detectors in a network (RS485 or Ethernet). This software provides the operating status of all connected detectors, and therefore allows operators to have a complete, up-to-date picture of the situation at the Critical Control Points.

This way, a single person is able to monitor all the Metal Detector CCPs, with a notable reduction in HACCP system management costs and improved application of the system itself.

In fact, as indicated in literature relating to the HACCP system, the biggest obstacles to implementing it are firstly the costs, especially in small and medium-sized businesses, and secondly the difficulties encountered in monitoring all the CCPs. Think for example of

companies where there are tens of Metal Detectors, and it becomes evident that the possibility of monitoring all these CCPs from a single workstation offers not only a saving in time, and therefore an economic advantage, but also an improvement in terms of real-time control efficiency.

CEIA's THS Production software automatically receives the malfunction signals, regarding for example the lack of power supply, air pressure or other fault, from the Metal Detectors connected in the network and immediately opens warning windows containing the data relating to the Metal Detectors and the fault conditions (see Fig. 2).

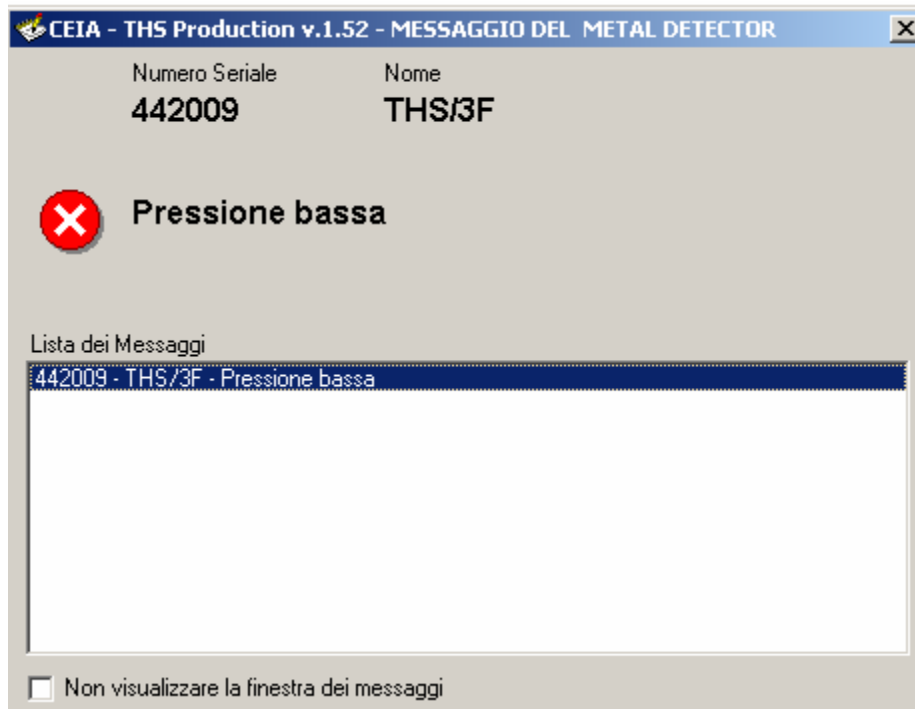


Fig. 2

Principle 6 – *Establishing checking procedures.*

The check consists of a group of methods, procedures and tests aimed at assessing the conformity of the HACCP System to the plan drawn up by the HACCP team and ensuring that the system operates correctly.

CEIA THS Metal Detectors are set up for two types of test:

1. Comparison with the signals received during the factory testing phase, which can be recalled via the Default product and checked with suitable test samples. The Default product is stored in memory during the Metal Detector test phase carried out in the factory, and the parameters associated with this product can not be modified by the user. By selecting this product, it is possible to

check whether the samples detected are those indicated in the Factory Acceptance Test (enclosed with the Metal Detector) in order to ensure that the detector has maintained correct calibration and settings.

2. Testing correct detection of the test samples relating to the current product.

For CEIA's THS Metal Detector the following quality tests are provided for:

- FE test;
- Non-FE test;
- SS test;

To carry out the sensitivity tests, CEIA has made available a wide range of samples and control kits in the following materials:

- Ferrous metal (AISI 420);
- Non-ferrous metal (Cu 93, Sn 6.6, P 0,03; or Cu70, 30Zn);
- Stainless steel (AISI 316).

All the samples are identified by a serial number, and their composition and electromagnetic response are certified.

In the HACCP Plan the frequency of the tests to determine the ability of the detector to keep to the established critical limits is specified.

It is possible to program CEIA THS Metal Detectors so that the detector itself requests that the operator carries out the quality test. This procedure consists of assigning a value different from zero to the "Test Interval" parameter: the Metal Detector then reminds the operator at that interval via a message on the display screen and a blue light signal.

It is also possible to carry out the quality tests at any time manually, even if an automatic test interval has been set. This conforms to the HACCP Plan, which specifies that, under certain conditions which may cause the product to exceed the critical limits, an additional test to the periodic ones should be carried out.

Principle 7 – *Establishing the documentation management system.*

The fundamental aim in this phase is the preservation of all records and documents that are generated during the application of the

HACCP Method in the company, that is to say all data deriving from the implementation of the HACCP System on the production lines.

All CEIA THS Metal Detectors are equipped with a non-volatile memory in which up to 1,000 events can be stored.

The recorded data allows complete documentation of what happens at the CPP in question. These records can be printed directly by connecting a printer to the RS232 port of the Metal Detector, or downloaded to a terminal to be archived in digital format as well.

The events stored in the buffer are as follows:

1. Metal Detector for food products:

- Alarm;
- Ejection;
- Parameter modification;
- Counter reset;
- Change of product;
- Autolearn;
- Metal Detector test;

2. Metal Detector for pharmaceutical products:

- Alarm;
- Ejection;
- Alarm reset;
- Parameter modification;
- Counter reset;
- Change of product;
- Autolearn;
- Metal Detector test;
- Metal Detector OFF;
- Metal Detector ON;
- User creation;
- User modification;
- User deletion;
- Login;
- Logout;
- Wrong login;
- Product creation;
- Product deletion;
- Test request;
- Fault;
- Fault reset.

Figures 3 and 4 show example extracts from the buffers relating to Metal Detectors THS/3F and THS/PH21

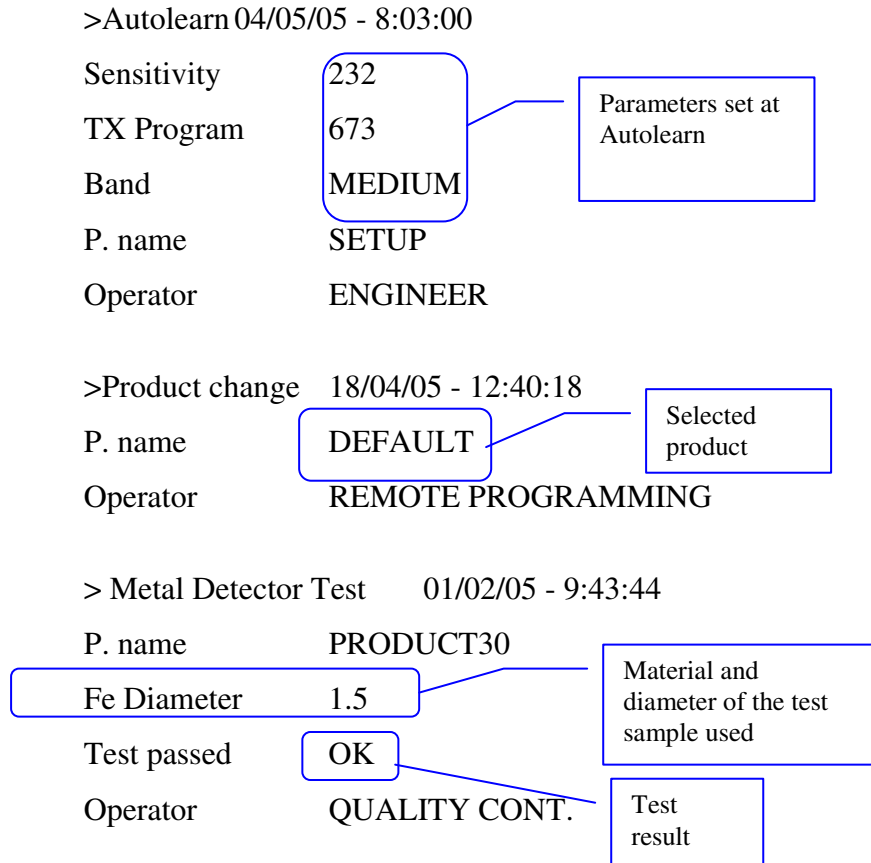


Fig. 3

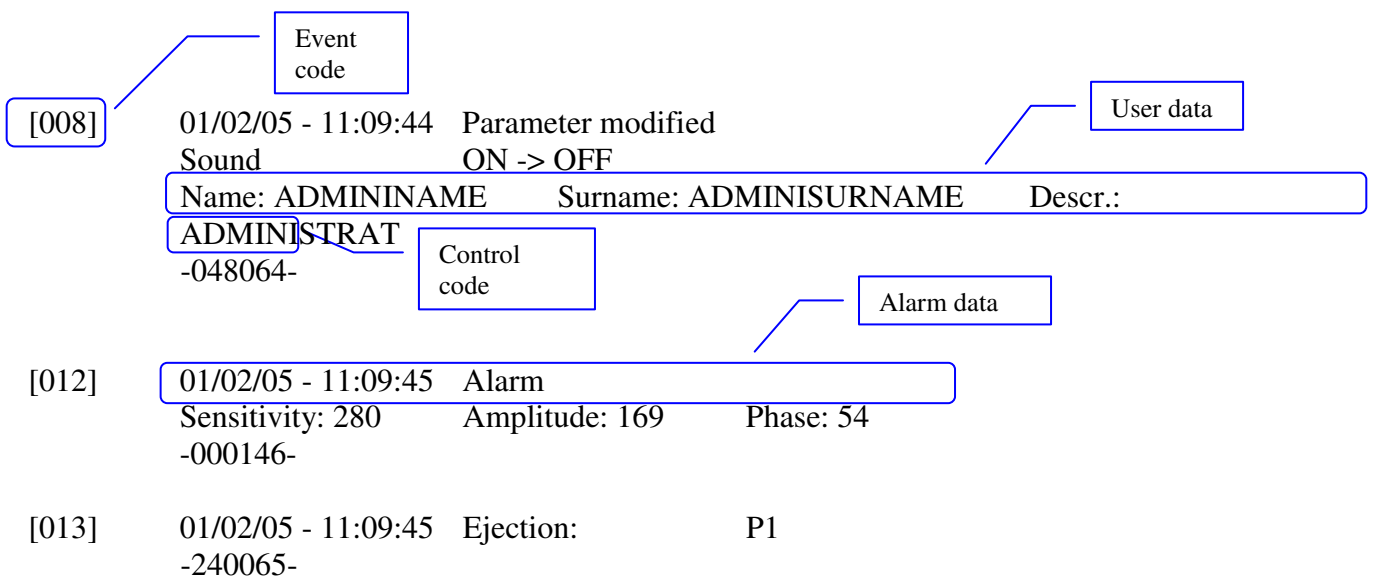


Fig. 4

CEIA's THS Production software also allows comprehensive management of all the data relating to the Metal Detectors in use in the company. The software carries out cyclical interrogations to record all the data originating from the detectors in a database. Personalized

reports can be created, including all the data in the database or only the data of interest for that particular document. The program can be set up to create and print the reports automatically (Fig. 5).

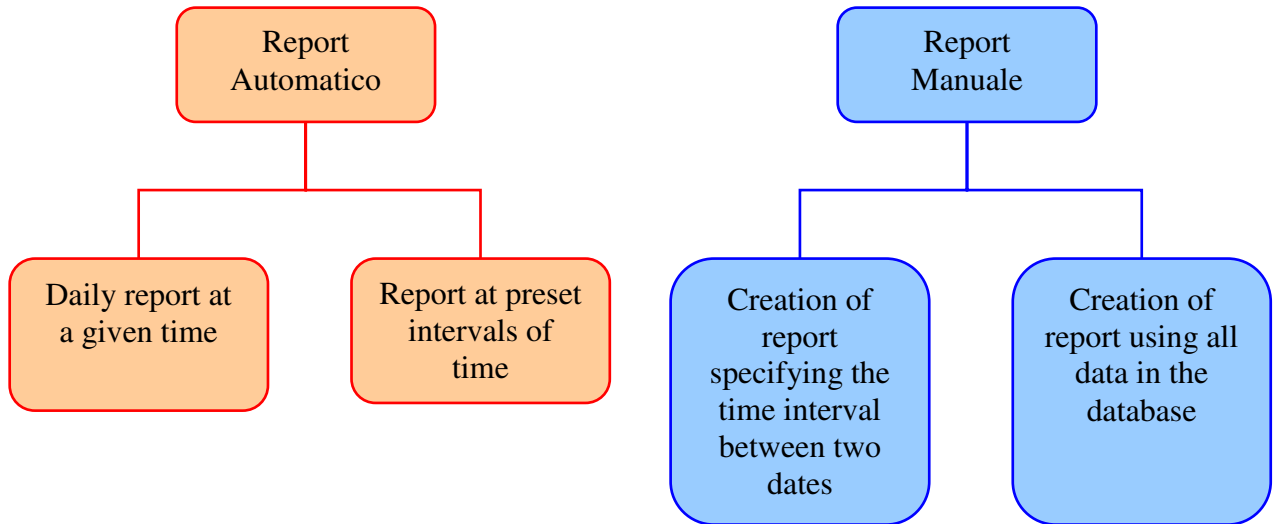


Fig. 5

It is also possible to create reports with data relating to several Metal Detectors, which may be useful when global assessment of the quantity of products that do not conform to the HACCP Plan is required.

Together with each report, a graph containing the quantity of products passing through the detector and of those ejected can also be created. (Fig. 6).

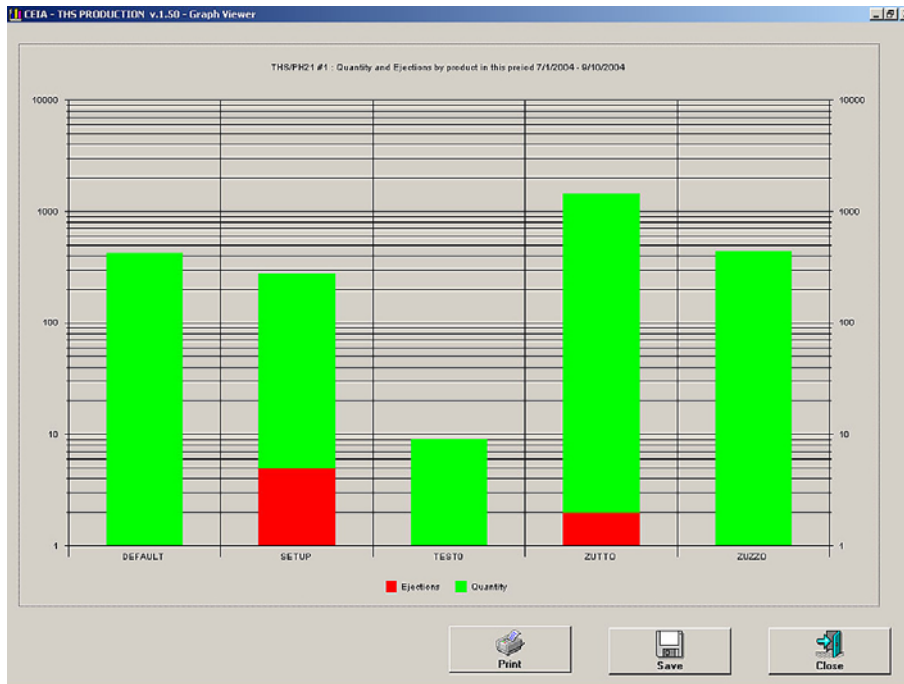


Fig. 6

In conclusion, it is important to highlight the fact that every document created using the CEIA THS Production software can be verified

at any time, via a control window, by checking every event in the database (Fig. 7).

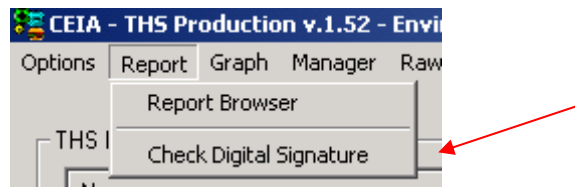


Fig. 7

The flexibility of the CEIA THS Production software also extends to allow exporting of the data to an external database (e.g. SQL Service) via a block program in the SQL language. This function is particularly useful for the IT staff who needs integration of the data relating to the Metal Detectors.

In Figure 8 there is an extract from the "Database Export Function Setup" screen, where you can see the variables associated with the ejection event and a typical instruction for entering the same into a remote table; it is obviously possible to select a similar window for each event type.

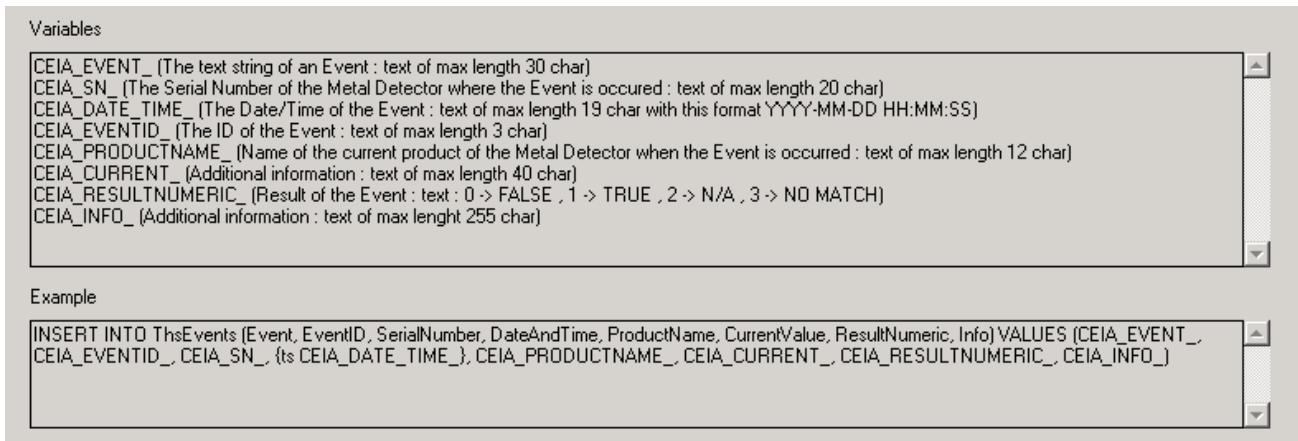


Fig. 8

Each HACCP plan includes a records structure, and therefore the possibility of having a database containing all data allows you firstly to create reports according to the specifications of each plan, and secondly to enter the information relating to the Metal Detectors into a document of a more general nature, which might include data originating from, for example, weighers, packaging machinery and so on.

As has been pointed out earlier, implementation of the HACCP System can be

hindered by initial costs and by the difficulties in application of the same. Manual management of documentation also gives rise to significant costs. The CEIA THS Production software allows not only savings in the time needed to manage the documentation, but also a significant qualitative improvement in the System itself: loss or alteration of data is not possible, given that the controls that are carried out conform to what is laid down in the directives of “Title 21 of the Code of Federal Regulation (CFR)”.

Bibliography

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7. *DIRECTIVE 2004/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 repealing certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC.*